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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability  
 Litigation

No. MD-15-02641-PHX-DGC

LISA HYDE and MARK HYDE, a married  
 couple,

**PLAINTIFFS' OPPOSITION TO  
 DEFENDANTS' MOTION *IN LIMINE*  
 6 TO EXCLUDE EVIDENCE OF AND  
 ARGUMENT ABOUT INFORMED  
 CONSENT**

Plaintiffs,

v.

(Assigned to the Honorable David G.  
 Campbell)

C.R. BARD, INC., a New Jersey corporation  
 and BARD PERIPHERAL VASCULAR, an  
 Arizona corporation,

(Oral Argument Requested)

Defendants.

**MEMORANDUM OF LAW IN SUPPORT**

The Court granted Defendants' Motion for Summary Judgment with respect to Plaintiffs' failure to warn claims focused only on Mrs. Hyde's implanting physician, Dr. Henry, finding that "Plaintiffs have failed to present any evidence that an inadequate warning caused Mrs. Hyde's injuries, as required under Wisconsin law." *See* Doc. 12007, at 14:19-21. The Court further concluded "Plaintiffs identify no evidence suggesting that Mrs. Hyde would have chosen not to receive a G2X filter had she been informed the device had an increased risk of adverse events relative to other IVC Filters. Nor do Plaintiffs present evidence from which a reasonable inference can be drawn that an adequate warning would have altered Dr. Henry's decision to use a G2X filter." *Id.* at 15:10-15. This Order

1 centers on the facts and circumstances regarding the decision to use the Bard G2X filter,  
2 and is silent about Bard's continuing duties to Plaintiffs, post-implantation.

3 Through common law decisions, Wisconsin imposes a duty to implement post-sale  
4 warnings and remedial measures. *See Kozlowski v. John E. Smith's Sons Co.*, 87 Wis. 2d  
5 882, 898-99, 275 N.W.2d 915, 922-23 (1979); *Sharp v. Case Corp.*, 227 Wis. 2d at 24, 595  
6 N.W.2d at 39 (1999). Factors to consider in determining whether there is a continuing post-  
7 sale duty to warn include "the nature of the industry, warnings given, the intended life of  
8 the machine, safety improvements, the number of units sold and reasonable marketing  
9 practices, combined with the consumer expectations inherent therein." *Id.*

10 Wisconsin federal courts have also recognized a manufacturer's post-sale duties. *See*  
11 *Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1318-19 (7th Cir. 1983)  
12 (recognizing a post-sale duty to warn or retrofit); *Olsen v. Ohmeda Div. of Boc Group, Inc.*,  
13 863 F. Supp. 870, 873-74 (E.D. Wis. 1994) (recognizing the post-sale duty to warn, but  
14 holding that the duty did not apply because the manufacturer was neither aware nor should  
15 have been aware of the defect before the injury).

16 Mrs. Hyde's Bard G2X filter was implanted on February 25, 2011 and removed in a  
17 complex procedure on August 26, 2014. Evidence will be presented that ongoing post-sale  
18 surveillance by Bard should have led to communications to physicians of the need to  
19 monitor patients who received Bard permanent, optional filters and that Bard filters were  
20 found to have increased risks caused by inherently dangerous design features of Bard filters,  
21 and the need to take steps to remove it before increasing the risk of suffering injuries. Bard  
22 should have also communicated the availability of safer alternative permanent and optional  
23 Bard filter designs and been forthright why these alternative designs were necessary. This  
24 information should have been conveyed to the medical community including Mrs. Hyde's  
25 post-implant treating physicians. Mrs. Hyde will testify at trial that had she been provided  
26 with this data known only to Bard, she would have taken steps to have the G2X filter  
27 removed long before her filter suffered the failures, and she suffered injury.  
28

1 Evidence provided from various Plaintiffs' experts regarding Bard's need to provide  
2 the medical community with additional information about the IVC filters so that physicians  
3 could engage in appropriate informed consent with patients regarding Bard's G2X IVC  
4 filter is still wholly relevant to Plaintiffs' case, and unaffected by the Court's prior ruling  
5 on Defendants' Motion for Summary Judgment.

6 Moreover, the punitive damages claim remains. Bard's failure to properly inform  
7 doctors and, by extension, patients of additional information about its IVC filters once  
8 implanted in Mrs. Hyde is direct evidence showing that Defendants acted maliciously  
9 toward Plaintiff and in intentional disregard of her rights. Wis Stat § 895.043. <sup>1</sup>"A review  
10 of our common law reveals that the phrase "disregard of rights" described a type of conduct  
11 that involved indifference on the defendant's part to the consequences of his or her actions."  
12 *Sharp*, 227 Wis.2d at 21, 595 N.W.2d 380.

13 Reports of Drs. Kinney, Roberts, Kalva, and Hurst regarding "informed consent"  
14 each show Bard's disregard toward the rights of all patients, including Mrs. Hyde. As  
15 opined by Drs. Kinney, Roberts and Kalva, patients need "the safety and effectiveness data  
16 that companies possess from their testing and monitoring of their medical devices,  
17 especially implanted devices such as IVC filters, to allow physicians to provide full and fair  
18 balanced informed consent to patients for whom these devices are prescribed and  
19 indicated." *See*, Def. Mot. in *Limine* No. 5, Exhibit A Report of Kinney, et al. at 9. These  
20 opinions are probative of informed consent and doctors'/patients' expectations, and Bard's  
21 choice to withhold the information was a disregard of Mrs. Hyde's rights as a patient.  
22 Withholding critical safety information amounts to a purposeful disregard of rights and  
23 shows that Bard was aware that withholding such information would impair doctor  
24 decisions regarding care of patients with filters, and result in harm to patients like Mrs.  
25 Hyde. Importantly, Bard's conduct need not be directly aimed at Mrs. Hyde herself.  
26 Therefore, the Court's Summary Judgement Order, which addressed Mrs. Hyde's choice at

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27 <sup>1</sup> A person acts in an intentional disregard of the rights of the plaintiff if the person acts with a  
28 purpose to disregard the plaintiff's rights or is aware that his or her acts are substantially certain to  
result in the plaintiff's rights being disregarded. Wis Stat § 895.043

1 implant, should not have bearing on post-sale evidence of Bard's conduct. *See, Strenke v.*  
2 *Hogner*, 279 Wis. 2d 52, 58 (Wis. 2005) (holding that a defendant's conduct giving rise to  
3 punitive damages need not be directed at the specific plaintiff in order to recover under the  
4 statute).

5 The same applies to Dr. Hurst's expert report, opinions, and potential trial testimony  
6 as it relates to "informed consent." Sections (b), (c), and (d) of Dr. Hurst's report go directly  
7 to Mrs. Hyde's punitive damages claims. *See*, Def. Mot. *in Limine* No. 5, Exhibit B, Report  
8 of Darren Hurst, M.D. The reasonable expectations of physicians for medical devices, the  
9 ethics behind the AMA codes as the standard of care relative to informed consent, patient  
10 communication, decision making, and opinions that Bard failed to properly notify doctors  
11 and patients of important safety information are clear and key examples of Bard showing  
12 an indifference to the consequences of its actions. Dr. Hurst sets forth AMA codes as the  
13 standard of care for informed consent and then opines that a failure to follow them while  
14 continuing to market a medical device (e.g., the G2X for the years that followed Mrs.  
15 Hyde's implantation) violated the standard of care. *Id.* at Section (c) at 7. In conjunction  
16 with the fact, as mentioned above, Mrs. Hyde would have taken steps to have her G2X  
17 removed before realizing its catastrophic failure, Bard's failure to comply with the  
18 aforementioned informed consent standards of care is evidence Plaintiffs can present to  
19 show that Bard was aware that their actions were substantially certain to result in Mrs.  
20 Hyde's rights being disregarded.

21 Plaintiffs respectfully request that Defendants Motion *in Limine* No. 6 be denied.  
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1 RESPECTFULLY SUBMITTED this 28<sup>th</sup> day of August 2018.  
2 GALLAGHER & KENNEDY, P.A.

3 By: /s/ Mark S. O'Connor

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13 **CERTIFICATE OF SERVICE**

14 I hereby certify that on this 28<sup>th</sup> day of August 2018, I electronically transmitted  
15 the attached document to the Clerk's Office using the CM/ECF System for filing and  
16 transmittal of a Notice of Electronic Filing.

17 /s/ Jessica Gallentine